



THE UNITED STATES OF AMERICA

TO ALL TO WHOM THESE PRESENTS SHALL COME:

UNITED STATES DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

September 15, 2004

THIS IS TO CERTIFY THAT ANNEXED HERETO IS A TRUE COPY FROM THE RECORDS OF THE UNITED STATES PATENT AND TRADEMARK OFFICE OF THOSE PAPERS OF THE BELOW IDENTIFIED PATENT APPLICATION THAT MET THE REQUIREMENTS TO BE GRANTED A FILING DATE.

APPLICATION NUMBER: 60/497,022

FILING DATE: *August 20, 2003*

RELATED PCT APPLICATION NUMBER: *PCT/US04/26981*

Certified by



Jon W Dudas

Acting Under Secretary of Commerce
for Intellectual Property
and Acting Director of the U.S.
Patent and Trademark Office



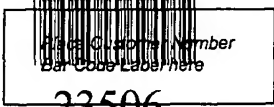
17264 U.S. PTO
08/20/03


PTO/SB/16 (05-03)
Approved for use through 4/30/2003. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

PROVISIONAL APPLICATION FOR PATENT COVER SHEET

This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53 (c).

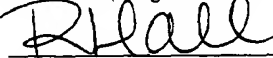
Express Mail Label No. EV349882542US

INVENTOR(S)					
Given Name (first and middle [if any])		Family Name or Surname		Residence (City and either State or Foreign Country)	
Richard W.		LEVAUGHN		Newnan, Georgia	
Gwenn E.		KENNEDY		Ellenwood, Georgia	
<input checked="" type="checkbox"/> Additional inventors are being named on the 1 separately numbered sheets attached hereto					
TITLE OF THE INVENTION (500 characters max)					
BLOOD SAMPLING DEVICE					
CORRESPONDENCE ADDRESS					
Direct all correspondence to:					
<input checked="" type="checkbox"/> Customer Number 23506 					
OR Type Customer Number here 23506					
<input type="checkbox"/> Firm or Individual Name PATENT, TRADEMARK OFFICE					
Address					
Address					
City		State		ZIP	
Country		Telephone		Fax	
ENCLOSED APPLICATION PARTS (check all that apply)					
<input checked="" type="checkbox"/> Specification Number of Pages 2021 <input type="checkbox"/> CD(s), Number					
<input checked="" type="checkbox"/> Drawing(s) Number of Sheets 9 <input type="checkbox"/> Other (specify)					
<input type="checkbox"/> Application Data Sheet. See 37 CFR 1.76					
METHOD OF PAYMENT OF FILING FEES FOR THIS PROVISIONAL APPLICATION FOR PATENT					
<input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27.					
<input checked="" type="checkbox"/> A check or money order is enclosed to cover the filing fees					
<input checked="" type="checkbox"/> The Director is hereby authorized to charge filing fees or credit any overpayment to Deposit Account Number: 50-1513					
<input type="checkbox"/> Payment by credit card. Form PTO-2038 is attached.					
FILING FEE AMOUNT (\$) 160					
The invention was made by an agency of the United States Government or under a contract with an agency of the United States Government.					
<input checked="" type="checkbox"/> No.					
<input type="checkbox"/> Yes, the name of the U.S. Government agency and the Government contract number are: _____					

Respectfully submitted,  [Page 1 of 2] Date 8/20/2003
SIGNATURE
TYPED or PRINTED NAME Arthur A. Gardner REGISTRATION NO. 33,887
(if appropriate)
TELEPHONE 770.984.2300 Docket Number: 2G02.1-082

CERTIFICATE OF EXPRESS MAILING UNDER 37 C.F.R. § 1.10

I hereby certify that this correspondence and the papers indicated to be attached are being deposited with the United States Postal Service as Express Mail, No. EV349882542 US in an envelope addressed to: Mail Stop Patent Application, Commissioner For Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450 on this 20th day of August, 2003.



Printed Name: Roseanne Hall

Aug 20, 2003
Date

16235 U.S. PTO
60/497022

08/20/03

PROVISIONAL APPLICATION COVER SHEET

Additional Page

PTO/SB/16 (05-03)

Approved for use through 4/30/2003. OMB 0651-0032

Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Docket Number 2G02.1-082

INVENTOR(S)/APPLICANT(S)		
Given Name (first and middle [if any])	Family or Surname	Residence (City and either State or Foreign Country)
Stephen	FLYNN	Peachtree City, Georgia
Carl E.	GRIFFIN	Marietta, Georgia
John C.	IRWIN	Woodstock, Georgia
Mary Kate	PYNES	Dallas, Georgia
Stephanie J.	CAMPBELL	Kennesaw, Georgia
Christopher J.	RUF	Marietta, Georgia
Mitchell A.	SOLIS	Cumming, Georgia
Avi M.	ROBBINS	Longwood, Florida
Jason R.	HEATH	Marietta, Georgia

[Page 2 of 2]

Number 1 of 1

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

CERTIFICATE OF EXPRESS MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service as "Express Mail Post Office To Addressee" in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231, on

Aug. 20, 2003

Express Mail No.: EV349882542US

Signature: Rilall

APPLICATION FOR LETTERS PATENT

UNITED STATES OF AMERICA

TO ALL WHOM IT MAY CONCERN:

Be it known that **Richard W. LEVAUGHN** of 68 Green Cabin Way, Talking Rock, Georgia 30175, USA; **Gwenn E. KENNEDY** of 5 North Lakeside Drive, Ellenwood, Georgia 30294, USA; **Christopher J. RUF** of 2160 Briarlake Trace, Atlanta, Georgia 30345, USA; **Mitchell SOLIS** of 1975 Lexington Lane, Cumming, Georgia 30004, USA; **Avi M. ROBBINS** of 539 Timber Ridge Drive, Longwood, Florida 32779, USA; **Jason R. HEATH** of 1675 Roswell Road, Marietta, Georgia 30062, USA; **Wolfgang OSTERTAG** of Kiefernweg 2, Gerstetten, Germany 89547; **Armin LOHRENGEL** of Hochfeldweg 21, Steinheim, Germany 89555; and **Herbert STOHR** of Signalstrasse 9, Grosskuchen, Germany 89522, have invented new and useful improvements in a

BLOOD SAMPLING DEVICE

for which the following is a specification.

GARDNER GROFF, P.C.
Paper Mill Village, Building 23
600 Village Trace, Suite 300
Marietta, Georgia 30067
(770) 984-2300

BLOOD SAMPLING DEVICE

Field of the Invention

The present invention relates generally to a medical sampling device, and more particularly to a multiple use device for minimally-invasive sampling of
5 blood and/or other body fluids for detection and analysis.

Background of the Invention

Various devices are known for sampling blood and other body fluids for analysis of the condition of a human or other animal. For example, U.S. Patent No. 5,971,941 is understood to show a cassette with test strips for placement by
10 a slider. A lancet pierces the skin surface so that blood can be obtained for analysis. The lancets are integrated on a test strip, and are positioned together with the test strip. Another embodiment is understood to show a disposable cylindrical insert having a lancet and a test membrane with an aperture for the lancet. The insert is inserted in a mounting cavity of a plunger or piston, which
15 forces the lancet outward for blood withdrawal. DE 198 19 407 A1 is understood to show a multiplicity of test strips with integrated lancets for insertion into an analysis device.

U.S. Patent No. 4,787,398 is understood to show a device with a plunger for directing a lancet outward, and has an evaluation system and a display
20 system. A replaceable unit is applied to the device for each measurement. The replaceable unit comprises the lancet and a test strip, which is wetted with blood. This replaceable unit is thrown away after each use. EP 0 449 525 A1 is understood to show a blood withdrawal system wherein a new lancet is inserted manually into a release device before each use. A test strip is then inserted into
25 the device. U.S. Patent No. 4,627,445 is understood to show a device for measuring blood sugar, with an integrated blood withdrawal unit. A new replaceable lancet and test elements must be installed to the device for testing, and afterward disassembled. U.S. Patent No. 5,951,492 is understood to show a disposable unit with a capillary tube and a test strip, to which sampled blood
30 taken is applied. The capillary tube includes a lancet. A new disposable unit is attached and removed before and after each measurement.

EP 0 877 250 A2, EP 0 949 506 A2 and EP 811 843 A2 are understood to show devices having a multiplicity of test elements arranged on a rotatable disk carrier. The test elements are brought successively into a working position and pushed out of the housing to be wetted with blood. U.S. Patent No. 6,228,100
5 U.S. Patent No. 4,794,926, are understood to show lancets arranged on a carrier, which is rotated with respect to a housing.

German Application DE 100 57 832 C1 is understood to show a lancing device of a known form. Other lancing devices understood to include multiple lancets are shown, for example, in U.S. Patent App. Serial No. 2002/0087056 A1
10 and WO 02/36010 A1. EP 0 589 186 B1 is understood to show a lancet with a removable protective cap. WO 01/66010 A1 is understood to include a multiplicity of lancets in a magazine, with an opening of the chamber closed by an elastic material, which is penetrated in the puncture process.

Known sampling devices have, however, not proven fully satisfactory to
15 all users for a variety of reasons. Accordingly, it is to the provision of an improved sampling device that the present invention is primarily directed.

Summary of the Invention

Briefly described, the present invention provides an improved sampling device, which is described herein by way of example embodiments
20 representative of the various aspects of the invention. In one aspect, the invention is a lancing device having a plurality of penetration elements or lancets arranged for sequential use in piercing the skin or other tissue of a human or animal subject for obtaining a sample of blood, interstitial fluid, and/or other body fluid(s). The invention optionally can include collection and/or analysis features
25 for collecting a sample of body fluid and/or analyzing one or more analytes or other characteristics of the sampled fluid. Certain embodiments are compact in size for convenience in portable personal use.

Example embodiments of the lancing device preferably include a housing and a multiplicity of lancets, with the multiplicity of lancets arranged on a carrier
30 or cassette and insertable, with the cassette, into the housing. A piston or plunger acts on a particular lancet when oriented in its working position. The sharp point of the working lancet is driven into a skin surface of a user positioned

over a lancing opening through the housing. The cassette is preferably removable from the housing after use for replacement.

In another aspect, the invention is a cassette comprising a plurality of lancets for penetrating the skin surface or other body portion of a human or
5 animal subject to obtain samples of blood and/or other fluids.

In example embodiments, the invention comprises a single compact device contained within a housing. In the housing, a working position of the lancet corresponds to a puncture position to be applied to the skin surface of a user. Each of a plurality of lancets is moved sequentially into the working
10 position in the device. When a lancet is positioned in its working position, the lancet is driven into the skin surface of a user.

Various embodiments of the invention provide an "all-in-one" device which is compact, i.e., is space-saving, and which is user-friendly and operator-friendly. Used lancets preferably are removed and replaced with unused lancets in a
15 simple manner as part of a cassette or cartridge. In example embodiments, the lancets are arranged into or onto a carrier or cassette, which can be inserted into the lancing device and which can be rotated or otherwise moved with respect to the housing, such that the lancets can be moved into working positions, located adjacent or apart from each other, as for example by rotating the carrier or
20 cassette within the housing. Therefore, the lancets are preferably arranged on a rotatable carrier and can be moved into the working position, as by a rotary movement. A lancet is in its working position if it can be moved out through the puncture position to puncture the skin.

Use of a rotatable carrier advantageously enables a compact design for
25 the housing, such that used lancets are moved out of the working positions by rotating the carrier. In this way they come automatically to a disposal position without a need to provide another separate translational process. Optionally, lancets and test elements can be arranged on the same carrier, so that the lancets and test elements can, for example, be removed as a single manually
30 operable unit from the packaging, and can be inserted into the analysis device in a single procedure. In other embodiments, the device includes lancets only, and serves as a lancing device without sampling and testing capability.

In still another embodiment of the invention, the lancets have removable caps at their free ends for protection against accidental sticks and to preserve sterility. The lancet can be forced through the protective capping means. It would also be considered advantageous, though, if the protective capping means can be removed from the particular lancet immediately before performing the puncture process. That can be accomplished in an advantageous manner by drawing back a particular protective cap slightly immediately before performing the puncture process. Then it proves advantageous if the particular protective capping means can be separated from the path of movement of the lancet after it has been removed from the particular lancet, and can be held in a holding space.

In another aspect, the invention preferably comprises a lancing device having a housing with an arming and firing mechanism and a cassette. The cassette is removably mounted within the housing, and includes a plurality of lancets each having a lancet body and a protective cap. The cassette defines a lancet firing position, with the lancets being movable in turn into the firing position, and the lancets being held in a non-firing plane and selectively moved into a firing plane so that a lancet to be fired is in the firing plane while the other lancets are not in the firing plane. It is preferred that the lancets are moved into the firing plane by a cam as the lancets approach the firing position. It is also preferred that the lancets that have yet to be fired are held in the non-firing plane, are moved into the firing plane by a cam as the lancets approach the firing position, and then after firing are moved back into the non-firing plane but in a different position such that re-firing of lancets is prevented.

Preferably, the lancets have an end shape that enables them to be captured positively and securely by the firing mechanism. In one form, this end shape is a T-shaped end to engage with and be captured by the arming and firing mechanism. In another form, this end is a ball-shaped end to engage with and be captured by the arming and firing mechanism.

Preferably, the lancets each include a removable cap, with the caps being pulled off the lancets just prior to the lancets being engaged and captured by the arming and firing mechanism. Advantageously, the cassette can include a cam track and each of the caps can include a follower which rides in and cooperates

with the cam track such that at a certain point as the cap moves along the cam track, the cap is pulled off the lancet.

Also, it is preferred that the lancets are held stationary while the lancet caps are pulled off therefrom. In this regard, the caps are pulled from the lancets, rather than the other way around. It is also preferred that the lancets are guided by the arming and firing mechanism during firing of the lancets, and not by the cassette. This provides a more accurated and repeatable guiding of the lancets. Inasmuch as guiding errors can lead to less than ideal translation of the lancet toward the skin, guiding errors should be minimized to minimize pain and discomfort associated with using such a device. This is so because if the sharp enters the skin with any instability or is oriented at an angle as it punctures the skin, the pain and discomfort experienced by the use can be greatly increased.

The lancing device can be configured such that the housing includes a base and a cover, with the cover having an opening and a movable door for selectively covering and uncovering the opening. Also, the base can include biasing elements for biasing the cassette toward the cover, which can help position the cassette within the housing and/or can assist in the subsequent removal of the cassette from the housing. Moreover, the lancing device cassette can initially include a breakaway tab to assist the user in placing the cassette in the housing. The breakaway tab can be broken off once the cassette is loaded in the housing.

These and other aspects, features and advantages of the invention will be understood with reference to the drawing figures and detailed description herein, and will be realized by means of the various elements and combinations particularly pointed out in the appended claims. It is to be understood that both the foregoing general description and the following brief description of the drawings and detailed description of the invention are exemplary and explanatory of preferred embodiments of the invention, and are not restrictive of the invention, as claimed.

Brief Description of the Drawing Figures

Figure 1 is a perspective, exploded top view of a sampling device according to one example embodiment of the invention.

Figure 2 is a perspective, exploded top view of a cassette portion of the sampling device of **Figure 1**.

Figure 3 is a top view of a lancet used in the cassette of **Figure 2**.

Figure 4A is a bottom view of the cassette portion of the sampling device of **Figure 2**.

Figure 4B is a perspective bottom view of a portion of the cassette portion of the sampling device of **Figure 3**.

Figures 5-7 are top views of the cassette portion of the sampling device of **Figure 1**, showing the uncapping of a lancet and the preparation and firing of the lancet.

Figure 8 is a bottom view of the cassette portion of the sampling device and depicts an arming mechanism portion thereof.

Figure 9 is a top, perspective view of the cassette portion of the sampling device.

Figure 10 is a top, perspective view of the cassette portion of the sampling device as shown in **Figure 9**, with some elements thereof removed to reveal a cam portion thereof for causing individual lancets to move into a firing plane.

Figures 11-17 are bottom views of the cassette portion of the sampling device of **Figure 1**, showing the operation of an arming mechanism in preparation for firing of a lancet.

Figure 18 is a top view of a sampling device according to a second example embodiment of the invention, with some elements omitted for clarity.

Figure 19 is a bottom view of a portion of the sampling device of **Figure 1**, with some elements omitted for clarity.

Figure 20 is a side sectional view of the device of **Figure 19**, taken along view lines A-A of **Figure 19**.

Figure 21 is a top view of a portion of the sampling device of **Figure 18**, with some elements omitted for clarity.

Figure 22 is a side sectional view of the device of **Figure 21**, taken along view lines **A-A** of **Figure 21**.

5

Detailed Description of Example Embodiments

The present invention may be understood more readily by reference to the following detailed description of the invention taken in connection with the accompanying drawing figures, which form a part of this disclosure. It is to be understood that this invention is not limited to the specific devices, methods, conditions or parameters described and/or shown herein, and that the terminology used herein is for the purpose of describing particular embodiments by way of example only and is not intended to be limiting of the claimed invention. Also, as used in the specification including the appended claims, the singular forms "a," "an," and "the" include the plural, and reference to a particular numerical value includes at least that particular value, unless the context clearly dictates otherwise. Ranges may be expressed herein as from "about" or "approximately" one particular value and/or to "about" or "approximately" another particular value. When such a range is expressed, another embodiment includes from the one particular value and/or to the other particular value. Similarly, when values are expressed as approximations, by use of the antecedent "about," it will be understood that the particular value forms another embodiment.

Figure 1, as a perspective exploded view, shows a blood analysis device according to one example embodiment of the invention, which as a whole is designated by the reference number 100. The blood analysis device 100 comprises a housing base 101 and a housing cover 102, with the base and the cover collectively comprising a housing. The blood analysis device 100 also includes a cassette or cartridge 150, which contains a plurality of lancets and can optionally contain a plurality of test elements (not shown in this figure). Unused lancets (and, if present, test elements) are stored in the housing, used, and, after use, discarded or disposed of by removing and replacing the entire

cassette 150. The blood analysis device 100 can further comprise an evaluation system, such as an electronic evaluation system and a display, such as in the form of a visually readable display to show the result of an evaluation. The device can be an "all-in-one" device, comprising lancing features and sample collection and analysis features. In alternate embodiments of the invention, the invention is a lancing device, comprising only the lancing features, substantially as described, and omitting the sample collection and analysis features.

The housing base 101 of the blood analysis device 100 preferably comprises a generally dish-shaped shallow pan, having the general size, shape and appearance of a short container. The housing base 101 includes a bottom 103 and a peripheral sidewall 104. An opening indicated generally at 106 is formed in the sidewall 104. Resilient fingers or springs, such as finger 107, are positioned on the interior of the bottom 103. These resilient fingers bias the cassette 150 upwardly in the direction of direction arrow 108. This biasing force assists in ensuring that the cassette 150 is properly positioned within the device 100 during use. The biasing force from the resilient fingers also assists in removing the cassette 150 for easy replacement.

The peripheral sidewall 104 has a top edge or rim 109 that is generally planar. However, a small landing or ledge indicated generally at 111 is positioned generally opposite, but not quite exactly opposite, the opening 106. The ledge 111 includes a smaller knob 112.

The upper cover portion 102 of the base is generally lid-like and includes a top or roof panel 121 having a central small bore 122, a large opening 123, and peripheral rim 124. A rotatable access door 126 is pivotally mounted to the cover 121 by way of a pin mounted in the small central bore 122. The access door 126 can be pivoted to selectively cover and uncover the opening 123.

A drive mechanism 130 is fitted within the underside of the cover 121. The drive mechanism 130 has an overall squat, cylindrical, plate-like shape. In this figure, much of the drive mechanism is concealed from view. The drive mechanism 130 includes an interior cover 131, an interlock system indicated generally at 132, and a slot 133 formed in a peripheral rim portion 134 of the interior cover 131. An arming mechanism indicated generally at 135 is fitted in

the underside of the drive mechanism 130. The arming mechanism includes an arming lever 136 and a rotatable pawl 137. The rotatable pawl 137 is generally L-shaped and pivots about a small pivot pin 138. A hammer 139 is provided for driving a lancet to be fired.

5 Optionally, a platen 140 is provided above the interior cover 131 and includes a number of chemical leads, such as chemical lead 141, for chemically or electrically communicating with a test element. A washer or spacer 142 is positioned above the platen 141 and beneath the exterior cover 102.

 As shown in this figure, the cassette or cartridge 150 is generally disk-
10 shaped, in the form of a short, squat cylinder. However, there is a small projection indicated generally at 151 that is adapted to be fitted within the opening 106 and to extend therethrough. This provides a positive means of accurately positioning the cassette 150 within the housing base 101 and ensuring a reliable, repeatable angular alignment therewith. To assist the user in
15 placing the cassette 150 in the housing base 101, a breakaway handle 152 is provided. The breakaway handle 152 includes a generally C-shaped peripheral rim 153 and an outwardly extending tab or tongue portion 154. It should be noted that once the cassette 150 is successfully placed within the housing of the device 100, the breakaway tab 154 can be removed. Removing the breakaway
20 tab results in a more compact unit and also makes it more difficult to reuse the cassette accidentally (which is to be avoided). It is preferred that reuse of the cassettes should be discouraged to the extent practicable, so as to minimize risk of contamination.

 Referring now to **Figure 2**, the cassette 150 is considered in more detail.
25 The cassette 150 includes a dish or bottom 156 that includes a floor 157 and an upstanding peripheral wall 158. As mentioned previously, there is a bump-out section 151 extending beyond the otherwise circular peripheral shape of the bottom 156. An opening or aperture 161 is formed in this bump-out section and provides means of a lancet to travel through the peripheral wall and to reach the
30 skin of a user. A generally bell-shaped cam 162 is mounted to the floor 157. A central column 163 is positioned in the middle of the floor 157 and includes a slot 164 that is aligned with the opening or aperture 161.

A carousel or carrier 170 is positioned within the bottom 156 and has a plurality of lancets mounted thereon, such as lancets 171-177. Each of the lancets includes three main components: a lancet body, and needle or sharp secured within the lancet body, and a removable cap that covers the tip of the sharp. Moreover, as shown in **Figure 3**, each lancet, indicated here at 180, has a novel shape and features, and includes a resilient lancet body 181, a metal sharp 182 rigidly secured within the body 181, and a removable cap 183 for concealing the tip of the sharp. The cap 183 includes retaining arms or cantilevers 184, 186 which terminate in cylindrical ends 188, 189 for cooperating with parts of the carousel to control the position of the caps. The cap 183 also includes a cam track follower 191, in the form of a short button, for following in a cam track, discussed below, to move the cap away from and back to the lancet body 181 as needed.

The lancet body 181 has a generally T-shaped end indicated generally at 192 and wings 193, 194. the shaped end 192 cooperates with the piston to be captured therein for movement therewith during firing. The wings 193, 194 cooperate with unshown guide elements to guide the up and down movement of the lancet body relative to the remainder of the cassette, as for when the lancet body is moved into the firing plane and then back to the storage plane.

Referring now to **Figure 4A**, the cassette 150 can be seen from the bottom. Each of the lancets includes a lancet retraction spring, such as retraction spring 201. These springs work to return the lancet after firing. Advantageously, the retraction springs are not formed as part of the lancets, reducing the unsprung weight thereof and improving the dynamic balance of the lancets. Referring now to **Figure 4B**, the cassette 150 can be seen from the bottom in perspective. The cassette 150 includes a number of guide blocks, such as guide blocks 202, 203, which help to control the position of the caps, such as protective cap 183. In this regard, the cantilevers or arms of the caps are received in cylindrical bores formed in the guide blocks. As shown in this figure, all of the caps, save one, are held fast against their respective lancet body. Thus, all but one of the lancets are capped. Likewise, all but one of the lancets are held in a storage plane (shown here to be the raised position, but since this is a view from the bottom, the storage plane is actually a lowered

position) spaced from the base of the cassette 150. The lone lancet which is uncapped is also in the firing position, nearest to the base of the cassette 150 (again, shown here in the lowered position, but since this is a view from the bottom, the firing plane is actually raised).

5 **Figures 5-7** depict the sequence of movements as a lancet moves to the firing position and then away from the firing position. As shown in **Figure 5**, as a lancet 171 approaches the firing position, its cap 183 is pulled off by the interplay of the cam track follower 191 (not seen in this figure) with the cam track 211. As can be appreciated from this figure, the cam track 211 is "bumped out" in the vicinity of region 151, which causes the cap to be pulled off the relatively
10 stationary lancet body as they both rotate in the counterclockwise direction of direction arrow 212.

As shown in **Figure 6**, as the lancet 171 moves into the firing position, with its cap 183 pulled off, the lancet is moved upwardly (in this view) out of the storage plane and into the firing plane by the engagement of the lancet against
15 the bell-shaped cam 162. As a result of this movement, the T-shaped end of the lancet body is captured in the correspondingly shaped opening in the piston and is ready to be cocked and fired. This is accomplished as the cassette 150 (and the lancet body) rotates in the counterclockwise direction of direction arrow 212.

20 As shown in **Figure 7**, after firing, as the lancet 171 moves from the firing position, its cap 183 is pushed back on and the lancet is moved downwardly (in this view) back to the storage plane. This movement back to the storage plane is permitted by the cam 162 and can be urged by a spring (unshown). As a result of this movement, the T-shaped end of the lancet body is released from
25 the correspondingly shaped opening in the piston. This is accomplished as the cassette 150 (and the lancet body) rotates in the counterclockwise direction of direction arrow 212.

As shown in **Figure 8**, alternatively, a cam path 220 can be provided to cock the lancing device, which cam path 220 can be located on the piston 221
30 and a post or pin 222 is provided on the arming lever 135. As the arming lever 135 rotates, the pin 222 passes over the cam path 220 and cocks the piston 221.

As depicted in **Figure 9**, during advancement of the cassette 151, a pin 231 on the cassette 151 follows in a slot in the housing. The slot for the pin 231 terminates at a position when the last lancet is in position for firing. The cassette 150 cannot be advanced any further, thereby preventing the reuse of the lancets in the cassette. Also, as previously described, the piston 221 captures the lancet as it moves up (or down, depending on one's perspective) into the firing plane. The piston 221 has a T-shaped opening 223 for securely capturing the end of the lancet. Advantageously, the lancet is vertically captured in the piston with a positive engagement, rather than being laterally positioned within the piston. Also, as shown in this figure, the lancet engages the piston in a T-shaped arrangement, but other arrangements are possible, such as a ball-and-socket arrangement.

As can be gleaned from **Figures 9 and 10**, a detent or knob 112 is provided in the arming lever slot and must be overcome to provide a uniform torque/speed for each user, thereby minimizing speed variations and helping to prevent unintentional needle bending as the cap is removed. **Figure 10** also more clearly shows the cam track 211 for causing the caps to be removed and replaced as the lancets move into and out of the firing position.

Figures 11 -- 17 depict the operation of the arming and cocking mechanism and the advancement of the cassette from one lancet to another. As shown in **Figure 11**, with the lancing device having been fired and ready to be advanced, the arming lever 136 is rotated clockwise in the direction indicated by direction arrow 241. As this happens, the rotatable pawl 137 is pulled along. As best seen in **Figure 12**, as the rotatable pawl 137 is pulled in the clockwise direction, it engages with teeth on the cassette and pulls the cassette clockwise as well. In this way, the cassette is rotated relative to the housing of the lancing device. Once the arming lever 136 has reached the position shown in **Figure 12**, it has fully advanced the cassette to bring a new lancet into the firing position. As this has happened, the lancet has been uncapped and has been moved from the storage plane into the firing plane, as previously described above. With the arming lever in this position of **Figure 13**, it is ready to be cocked, such as is done by pulling the arming lever laterally in the direction of direction arrow 242 as shown in **Figure 14**. In a simplified form of the invention,

the arming lever can be simply released, driving the piston forwardly in the direction of direction arrow 243. Alternatively, the arming 136 can be gently released to reach the position of **Figure 15**, and then a separate, unshown, trigger can be operated to fire the device. To return the arming lever 135 to the
5 starting position, it is rotated counterclockwise in the direction of direction arrow 244 until it reaches position of **Figure 17**.

Figure 18 shows an alternative embodiment of the invention in which the T-shaped ends of the lancets are replaced with balls and the T-shaped opening formed in the piston is replaced with a socket. Thus, as shown in this figure, a
10 ball and socket arrangement replaces the T-shaped arrangement of the previous embodiment.

Figure 19 is a bottom view of a portion of the lancing device 100 of **Figure 1** according to a modified form of the invention, with some elements omitted for clarity and **Figure 20** is a side sectional view of the device of **Figure**
15 **19**, taken along view lines **A-A** of **Figure 19**. As shown in these figures, alternatively, the drive spring can be loaded from the back, rather than pulling the piston back to load the back of the springs. In this arrangement, pushing the activation button cocks and fires the device all in one motion.

Figure 21 is a top view of a portion of the sampling device of **Figure 18**,
20 with some elements omitted for clarity and **Figure 22** is a side sectional view of the device of **Figure 21**, taken along view lines **A-A** of **Figure 21**. As shown herein, a cantilever 252 on the cassette 150 drops into position when the last lancet is in the firing position to prevent further advancement of the cassette 150. As indicated generally at 260, after use, the lancets are returned to the storage
25 plane, but are offset from their original positions so that they will not be able to be aligned with the piston a second time and therefore cannot be reused. As best seen in **Figure 22**, the firing plane **FP** is common to both the lancet to be fired and the piston, while the storage plane **SP** is offset therefrom. As is clearly shown in this figure, the cap 183 is held in the storage plane **SP**, even as its
30 associated lancet 171 is in the firing plane **FP** for firing. Meanwhile, the other lancets, such as lancet 175, are held in the storage plane **SP**.

To recap, some notable features of the invention as shown in the Figures include the following:

- 5 a. To assist in lancet retraction, a cantilever is provided on the cartridge body or cassette body, rather than locating it on the lancet.
- b. The lancets are stored in a plane that is offset from the firing plane. When the lancet is advanced into position for firing, it is pushed to the firing plane to align it with the piston and is fired.
- c. After firing, the lancet is moved out of the firing plane and is stored in
10 this storage plane.
- d. The cassette is dropped into the housing from above and the lancets engage positively with the piston or plunger.
- e. The lancet is vertically captured in the piston with a positive engagement, rather than being laterally positioned within the piston.
- 15 f. A lancet engages the piston in either a T-shaped arrangement or in a ball-and-socket arrangement.
- g. The lancet cap is removed prior to the lancet being placed into the firing position.
- h. Cantilevers (arms) are located on each side of the lancet cap to help
20 maintain the position of the caps.
- i. Rather than keeping the unfired lancets in the firing plane and moving them out of the firing plane after firing, the lancets are held in a plane other than the firing plane and then moved to the firing plane for firing.
- j. The lancet to be fired next is held relatively stationary while the lancet
25 cap is removed. In this regard, the cap is pulled off the lancet rather than the lancet being pulled off the cap. It should be noted that this happens while the lancet and the cap together are rotating with the carrier but within that rotational movement, the lancet is held relatively still while the cap is moved radially away from the lancet.

k. The lancet cap cantilevers are assembled to the cassette to retain the cap at all times and to help force the cap off the lancet.

l. The lancet cap guide or cam track is a separate part of the cassette, rather than being a feature of the cap itself.

5 m. The lancet is retained and guided securely by the piston and is not guided by the cartridge or cassette. During the firing of a lancet, all guidance is provided by the piston guidance, rather than any guidance being provided by the cassette.

10 n. The central post in the cassette prevents other lancets from interfering with the piston before or after the firing of a lancet.

o. Fingers or springs positioned in the housing base push on the cassette upwardly to position the cassette and to ensure full engagement of the arming lever with the cassette.

15 p. A breakaway feature is located on the cassette to assist in the insertion of the cassette in the device. When the breakaway feature has been removed, it is difficult to properly insert a cassette, which discourages the improper reuse of cassettes.

20 q. Spring fingers in the base of the housing also push the cassette upwardly when the housing is open, thereby assisting in the removal of the used cassette from the housing.

r. To arm the lancing device, the arming lever is rotated within a slot to advance the cassette and to engage the lancet and lancet holder. The arming lever is then pulled back to cock the piston.

25 s. Alternatively, a cam path can be provided to cock the lancing device, which cam path can be located on the piston and a post or pin is provided on the arming lever. As the arming lever rotates, the pin passes over the cam path and cocks the piston.

30 t. Alternatively, the drive spring can be loaded from the back, rather than pulling the piston back to load the back of the springs. In this arrangement, pushing the activation button cocks and fires the device all in one motion.

u. During advancement of the cassette, a pin on the cassette follows in a slot in the in the housing. The slot for the pin terminates at a position when the last lancet is in position for firing. The cassette cannot be advanced any further, thereby preventing the reuse of lancets.

5 v. After firing, as the next lancet is moved into the firing position, the used lancet is returned to the storage position and is recapped to prevent the reuse of the lancet and to prevent accidental needle sticks upon removal of the used cassette.

10 w. A cantilever on the cassette drops into position when the last lancet is in the firing position to prevent further advancement of the cassette.

x. The arming lever does not have a ledge to engage with when the last lancet is in the firing position, so the arming lever cannot advance the cassette any further.

15 y. After use, the lancets are returned to the storage plane, but are offset from their original positions so that they will not be able to be aligned with the piston a second time and therefore cannot be reused.

z. The lancing device includes an access cover that can be rotated out of the way to provide access to a sensor disk for use and then rotated back to close the sensor cavity.

20 aa. Chemical leads can be provided to connect a blood collection area with the processing device (optional), or, in an alternative embodiment, chemical leads can provide positive connections between a blood receptacle and electrically conductive leads.

25 ab. The lancet cap blocks the needle/sharp/blade to prevent the needle/sharp/blade from extending beyond lancing device.

ac. A detent is provided in the arming lever slot and must be overcome to provide a uniform torque/speed for each user, thereby minimizing speed variations and helping to prevent unintentional needle bending as the cap is removed.

ad. An interlock system is provided in the arming lever to prevent the arming lever from sliding through its slot once the device is cocked. Once the lancing device has been fired, the arming lever is free to slide once again.

ae. The arming lever has a cantilever portion that slides through a path in the housing as the arming lever slides through its slot. When the arming lever is advancing the cassette, the cantilever passes through a path with several ledges or teeth for engagement so the arming lever will not return to the starting position before it slides through its full stroke. The cantilever is disengaged from the ledges or teeth when the arming lever is pulled back to cock the lancing device and the arming lever is free to be returned to the start position.

While the invention has been described with reference to preferred and example embodiments, it will be understood by those skilled in the art that a variety of modifications, additions and deletions are within the scope of the invention, as defined by the following claims.

What is Claimed is:

1. A lancing device comprising:

a housing having an arming and firing mechanism; and

a cassette removably mounted within said housing, said cassette comprising a plurality of lancets each having a lancet body and a protective cap, the cassette defining a lancet firing position, with the lancets being movable in turn into the firing position, and the lancets being held in a non-firing plane and selectively moved into a firing plane so that a lancet to be fired is in the firing plane while the other lancets are not in the firing plane.
2. The lancing device of Claim 1, wherein the lancets each have a T-shaped end to engage with and be captured by the arming and firing mechanism.
3. The lancing device of Claim 1, wherein the lancets each have a ball-shaped end to engage with and be captured by the arming and firing mechanism.
4. The lancing device of Claim 1, wherein the lancets each include a removable cap, with the cap being pulled off the lancet just prior to the lancet being engaged and captured by the arming and firing mechanism.
5. The lancing device of Claim 4 wherein the cassette includes a cam track and each of the caps includes a follower that rides in and cooperates with the cam track such that at a certain point as the cap moves along the cam track, the cap is pulled off the lancet.
6. The lancing device of Claim 5 wherein the lancet to be fired is held relatively stationary while the lancet cap is pulled off therefrom.
7. The lancing device of Claim 1, wherein the lancets are guided by the arming and firing mechanism during firing of the lancets.
8. The lancing device of Claim 7, wherein the lancets are guided by the arming and firing mechanism during firing of the lancets and are not guided by any portion of the cassette during the firing of the lancets.
9. The lancing device of Claim 1, wherein the housing includes a base and a cover.

10. The lancing device of Claim 1, wherein the housing includes a base and a cover, with the cover having an opening and a movable door for selectively covering and uncovering the opening.

11. The lancing device of Claim 9, wherein the base includes biasing elements for biasing the cassette toward the cover.

12. The lancing device of Claim 1, wherein the cassette initially includes a breakaway tab to assist the user in placing the cassette in the housing, and wherein the breakaway tab can be broken off once the cassette is loaded in the housing.

13. The lancing device of Claim 1, wherein the lancets are moved into the firing plane by a cam as each lancet approaches the firing position.

14. The lancing device of Claim 1, wherein the lancets that have yet to be fired are held in the non-firing plane, are moved into the firing plane by a cam as the lancets approach the firing position, and then after firing are moved to the non-firing plane but in a different position such that re-firing of lancets is prevented.

15. The lancing device of Claim 1, wherein the arming and firing mechanism comprises a piston and a cocking mechanism.

16. The lancing device of Claim 15, wherein actuation of the cocking mechanism advances the cassette to sequentially engage each of said plurality of lancets with said piston.

17. The lancing device of Claim 1, wherein said cassette comprises a plurality of lancets radially arranged about an axis.

18. The lancing device of Claim 15, wherein the lancet and the piston comprise interengaging coupling elements.

19. A lancing cassette comprising:

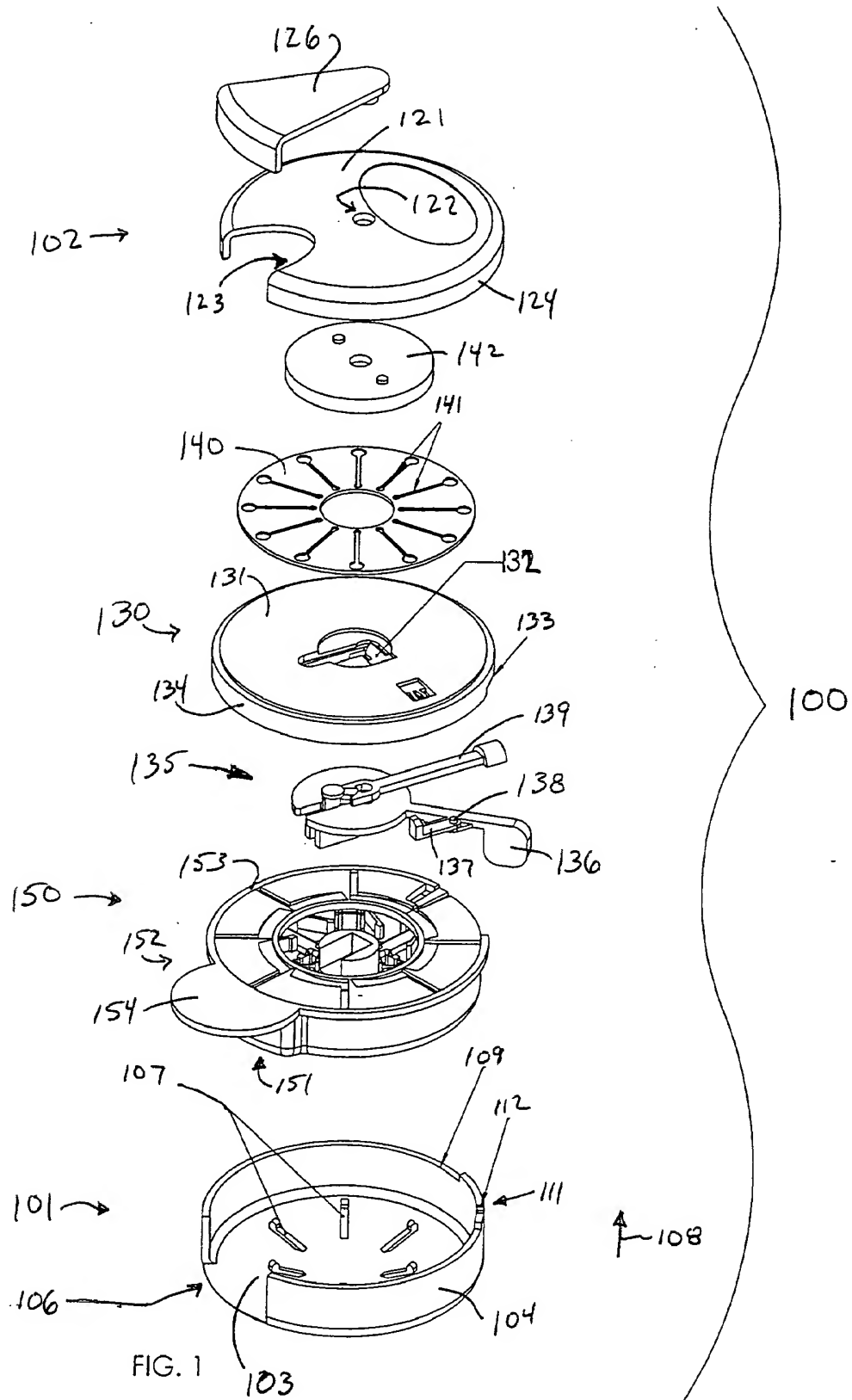
a plurality of lancets each having a lancet body and a protective cap mounted thereon;

a cam mechanism for moving the protective cap away from each said lancet body prior to firing and for returning the protective cap to the lancet body after firing.

ABSTRACT

A lancing device for sampling blood or other body fluid of a subject includes a housing and a one-time use cassette. The cassette contains a plurality of lancets. The lancets are held in a storage plane and just prior to
5 being fired are moved to a firing plane for firing by an arming and firing mechanism. After firing, the lancet is returned to the storage plane. Each lancet includes a protective cap that is pulled off the lancet just prior to firing and then is returned to the lancet after firing.

1/9



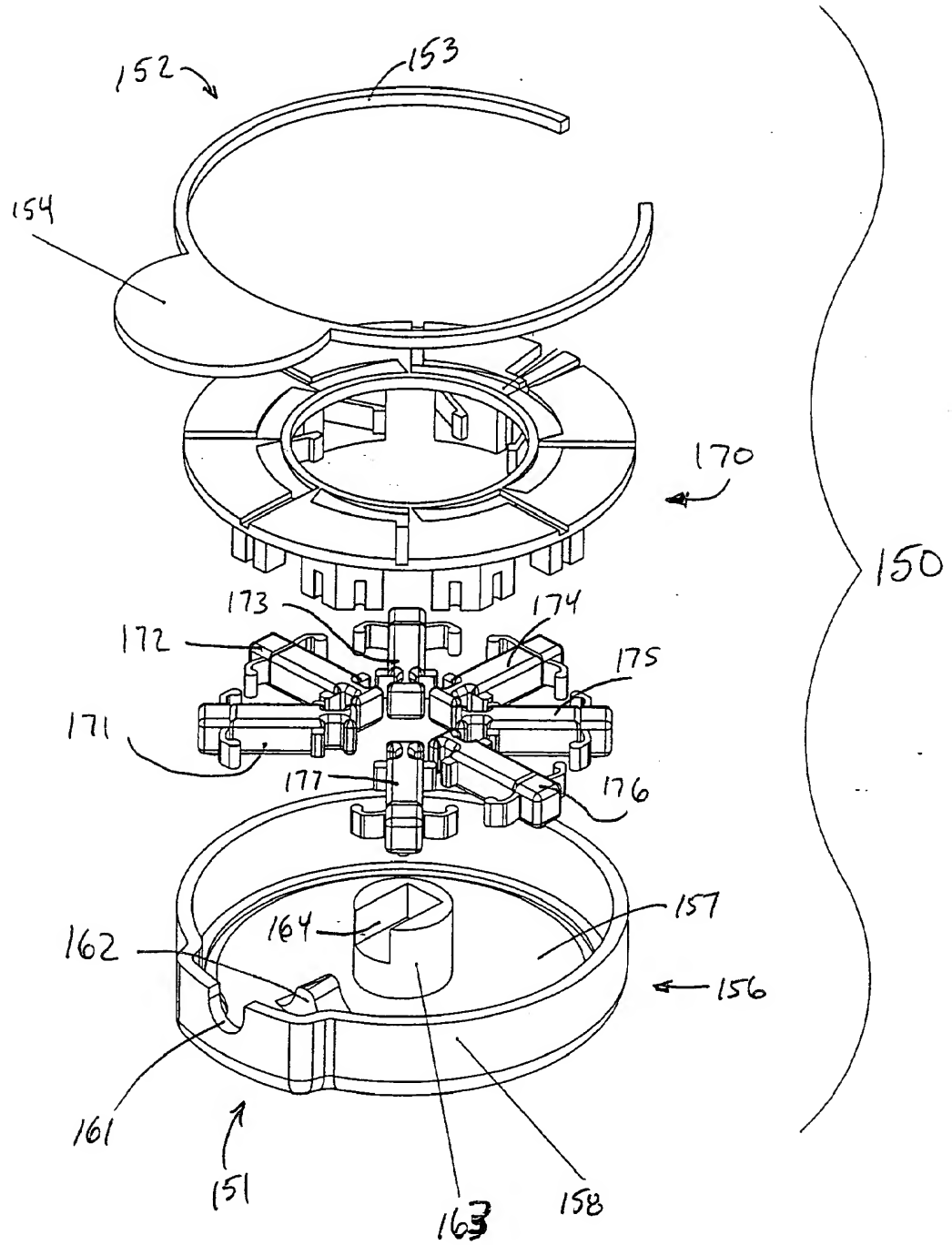
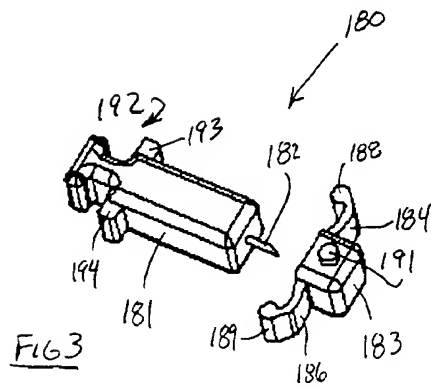
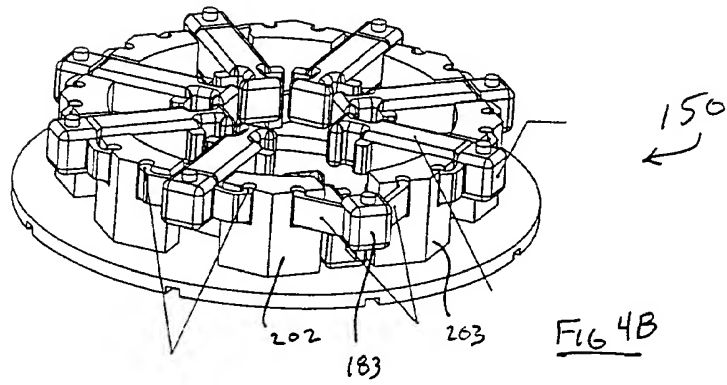
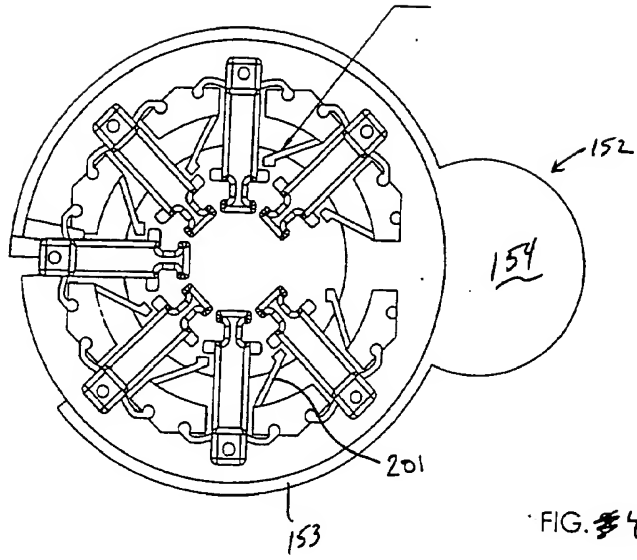


FIG. 2



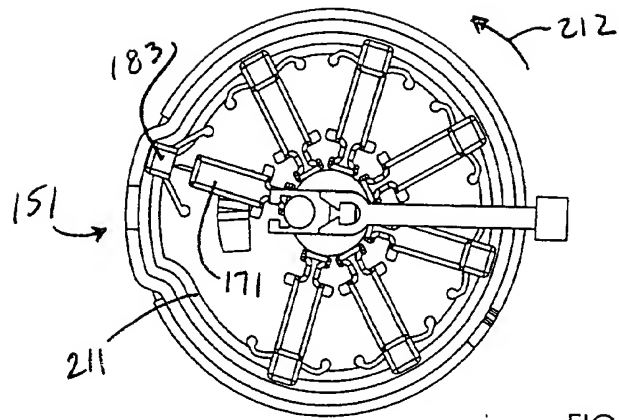


FIG. 5

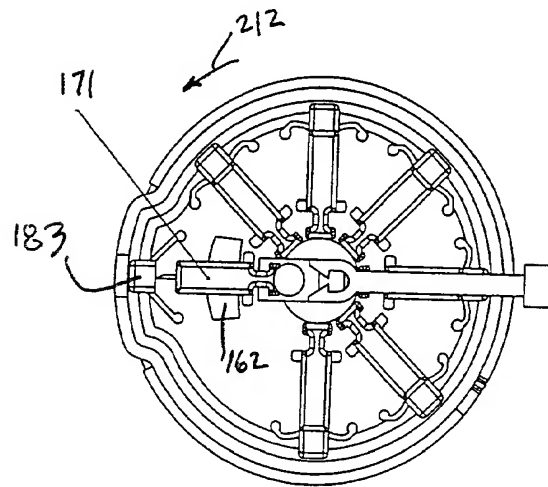


FIG. 6

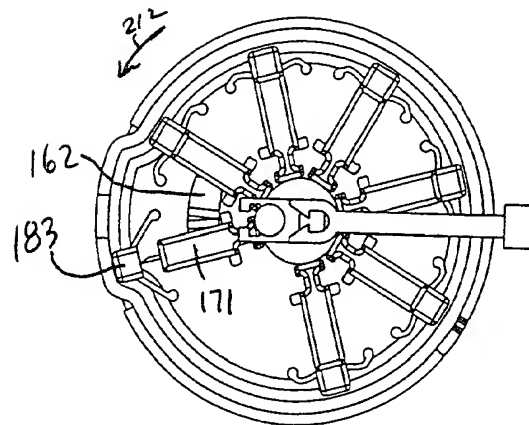
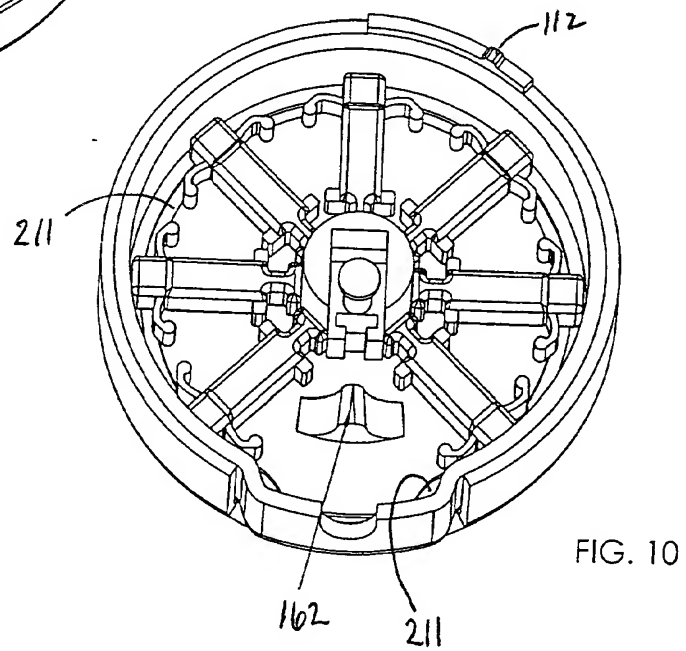
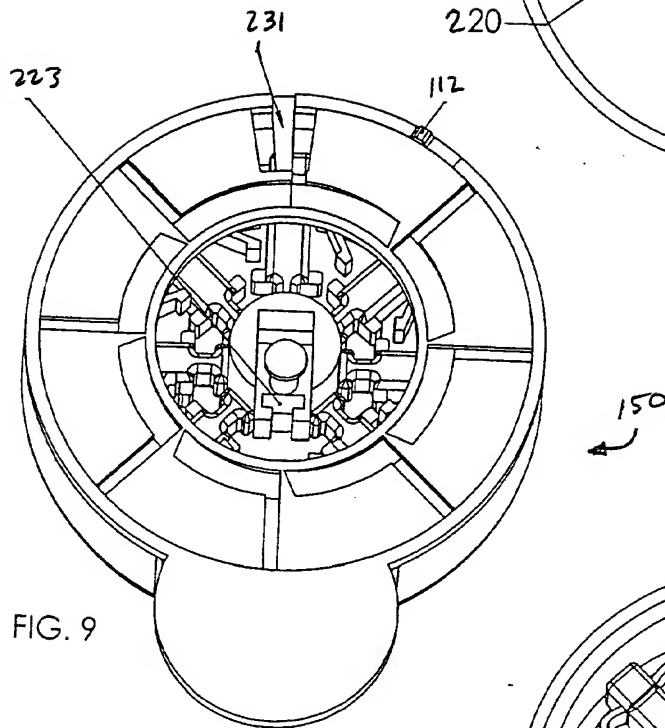
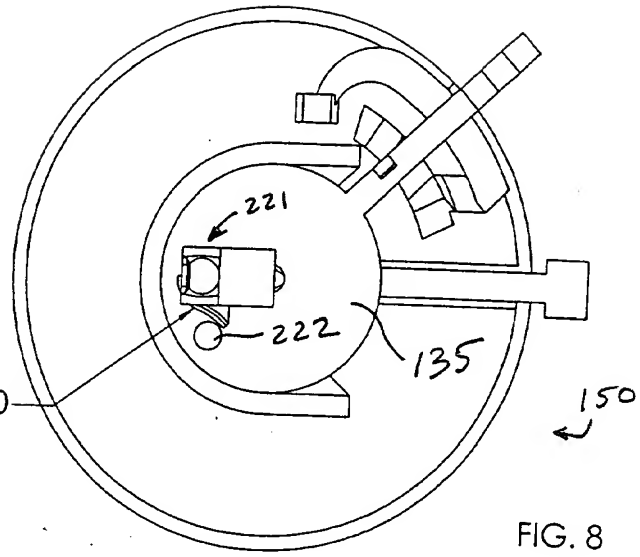


FIG. 7



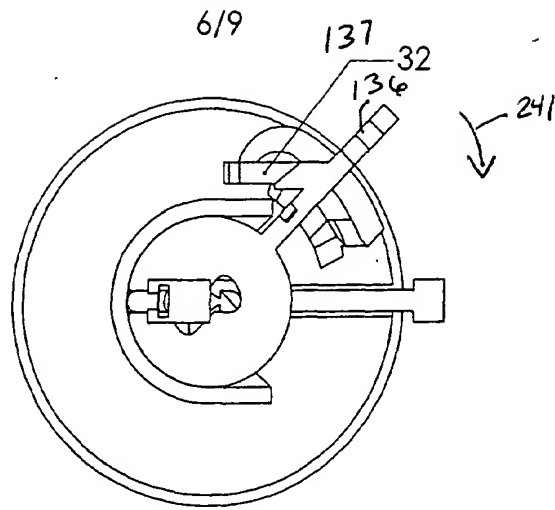


FIG. 11

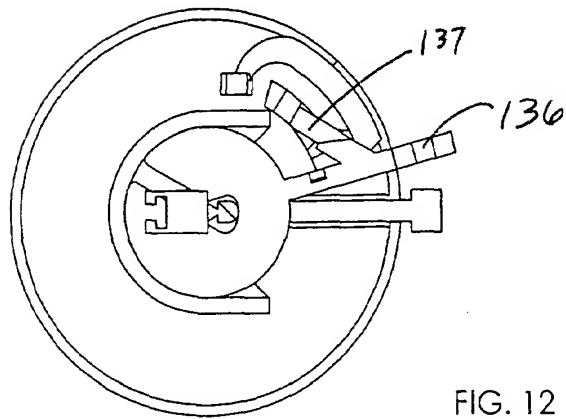


FIG. 12

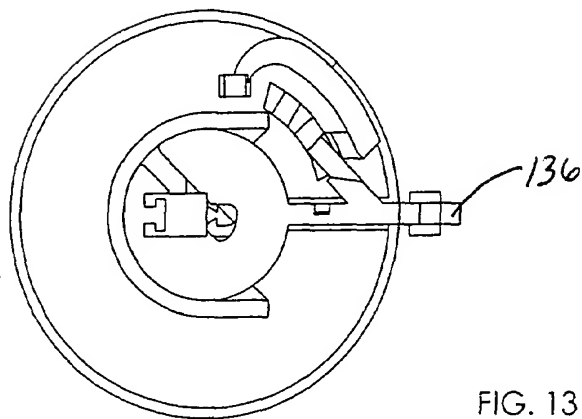
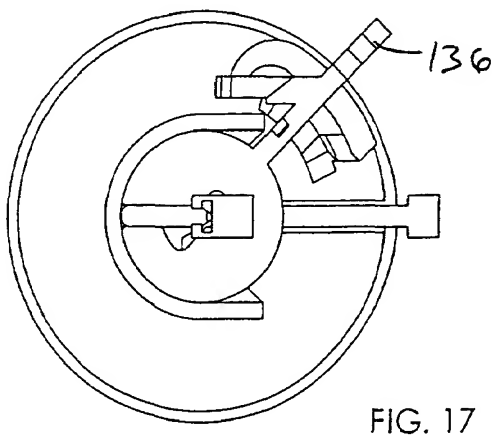
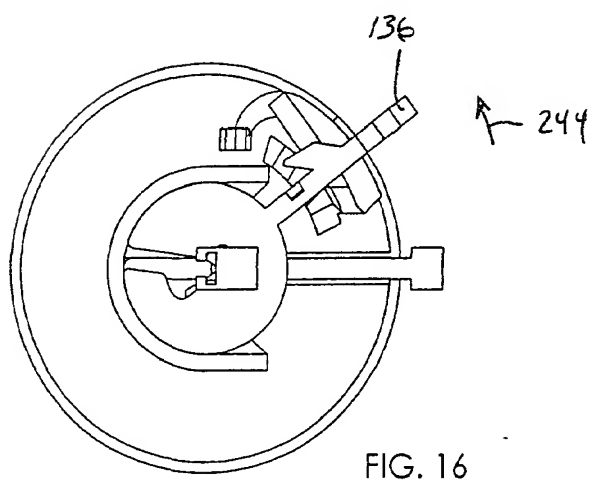
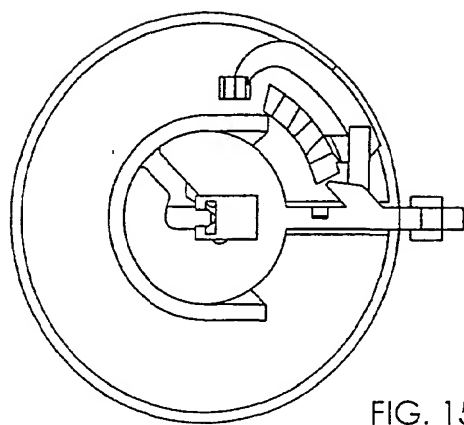
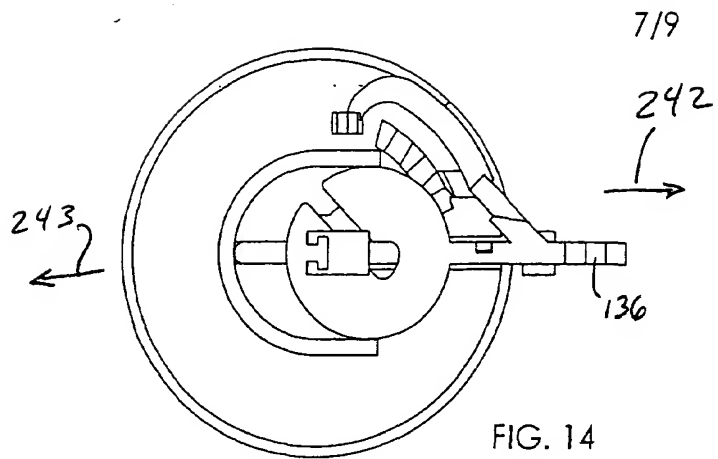


FIG. 13



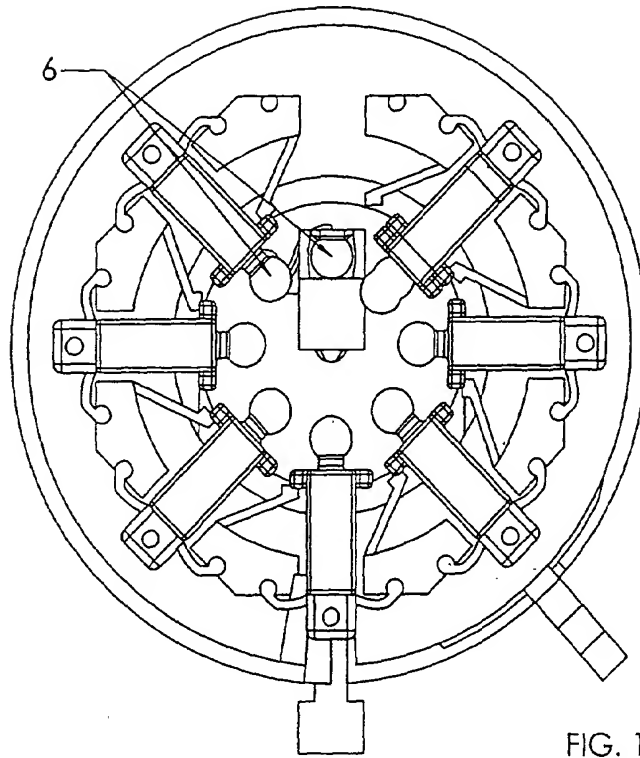


FIG. 18

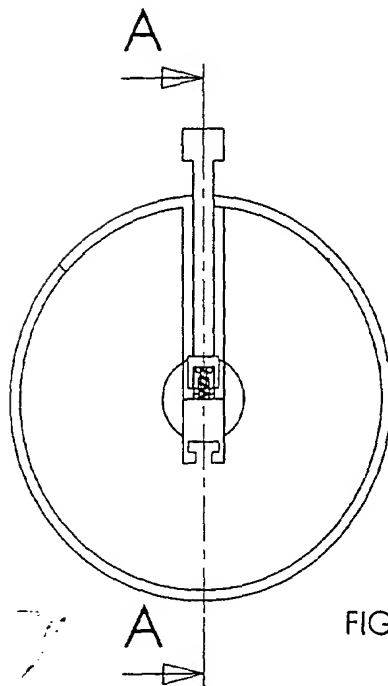


FIG. 19

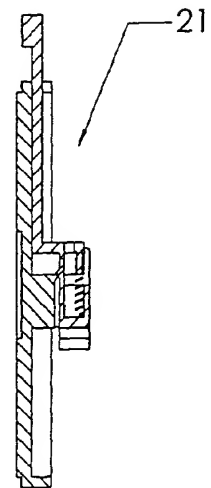


FIG. 20
SECTION A-A

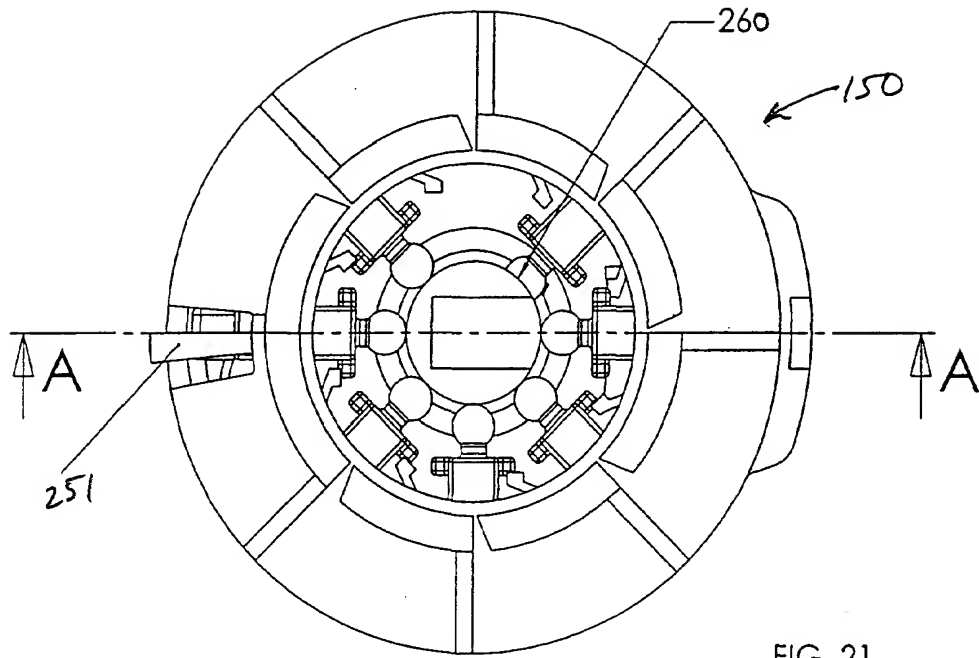


FIG. 21

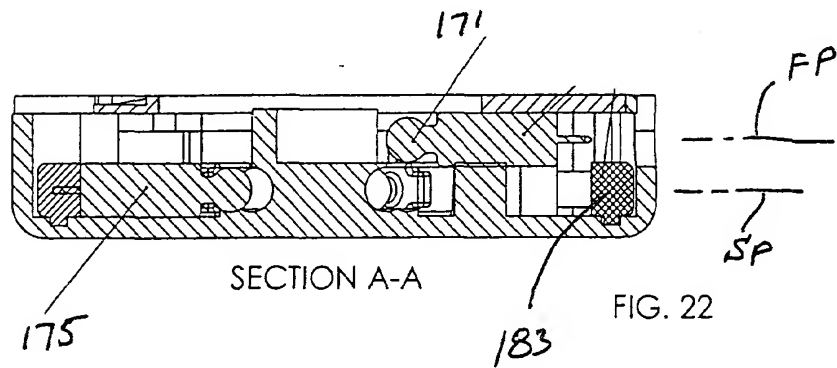


FIG. 22

Document made available under the Patent Cooperation Treaty (PCT)

International application number: PCT/US04/026981

International filing date: 19 August 2004 (19.08.2004)

Document type: Certified copy of priority document

Document details: Country/Office: US
Number: 60/497,022
Filing date: 20 August 2003 (20.08.2003)

Date of receipt at the International Bureau: 23 September 2004 (23.09.2004)

Remark: Priority document submitted or transmitted to the International Bureau in compliance with Rule 17.1(a) or (b)



World Intellectual Property Organization (WIPO) - Geneva, Switzerland
Organisation Mondiale de la Propriété Intellectuelle (OMPI) - Genève, Suisse